

ARKANSAS DEPARTMENT OF HEALTH
ENVIRONMENTAL HEALTH PROTECTION

RULES AND REGULATIONS

GOOD MANUFACTURING PRACTICES



Promulgated Under Authority of Ark. Code Ann. §§ 20-7-101 through 20-7-130, §§ 2056-201 through 20-56-223, and §§ 20-57-201 through 20-57-208.

Table of Contents

NOTICE: Section numbers in this Regulation coincide with the Federal Good Manufacturing Practices therefore the numbers are not sequential.

SECTION 110.0	AUTHORITY	1
SECTION 110.1	PURPOSE	1
SECTION 110.2	SALVAGE EXCLUSION	1
SECTION 110.3	DEFINITIONS	2
SECTION 110.10	PERSONNEL	3
SECTION 110.19	AGRICULTURE EXCLUSION	4
SECTION 110.20	PLANT AND GROUNDS	5
SECTION 110.35	SANITARY OPERATIONS	6
SECTION 110.37	SANITARY FACILITIES AND CONTROLS	8
SECTION 110.40	EQUIPMENT AND UTENSILS	9
SECTION 110.80	PROCESSES AND CONTROLS	10
SECTION 110.93.	WAREHOUSING AND DISTRIBUTION	14
SECTION 110.110	NATURAL AND UNAVOIDABLE DEFFECTS	14
SECTION 111.1	PERMITS, INSPECTIONS AND PLAN REVIEW	15
SECTION 111.2	SPECIAL RISK SITUATIONS	16
SECTION 111.3	PENALTIES AND INJUNCTIONS	17
SECTION 111.4	REPEAL	17

SECTION 110.0 AUTHORITY

The following Rules and Regulations Pertaining to Review of Plans for Food Processing Establishments are duly adopted and promulgated by the Arkansas State Board of Health pursuant to the authority expressly conferred by the Laws of the State of Arkansas, including, without limitation, Act No. 96 of 1913 (Ark. Code Ann. § 20-7-109) and Act 415 of 1953 (Ark. Code Ann. §§ 20-56-201 through 20-56-223).

SECTION 110.1 PURPOSE

The Arkansas State Board of Health finds and declares that a uniform statewide code is needed to regulate all food manufacturing, processing, packing, holding, or transporting operations conducting business in the State of Arkansas, to provide for uniformity in inspecting of such establishments, and to protect the health of consumers by preventing the sale or distribution of foods which have become adulterated or misbranded.

SECTION 110.2 SALVAGE EXCLUSION

Establishments engaged exclusively in the salvaging of food products under the provisions of the Arkansas Food Salvage Act, Act 241 of 1963 and in accordance with the Rules and Regulations promulgated there unto, are herewith excluded from the provisions of these Rules and Regulations.

SECTION 110.3 DEFINITIONS

For the purpose of these Regulations, the following terms are defined:

- A. "Acid Food or Acidified Food" means foods that have an equilibrium pH of 4.6 or below.
- B. "Act" means Act 415 of 1953, the Arkansas Food, Drug and Cosmetic Act.
- C. "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- D. "Batter" means a semi fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- E. "Blanching", except for tree nuts and peanuts, means a prepackaging heat treatment of food stuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or bio-chemical changes in the food.
- F. "Critical Control Point" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or filth in the final food or decomposition of the final food.
- H. "Department" means the Arkansas Department of Health and its duly designated representatives.
- J. "Food" means any raw, cooked, or processed edible substance, ice, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption.
- K. "Food Contact Surfaces" means those surfaces of equipment and utensils with which food normally comes in contact, and those surfaces from which food may contact drain, drip, or splash back onto surfaces normally in contact with food.
- L. "Lof" means the food produced during a period of time indicated by a specific code.
- M. "Microorganism" means yeasts, molds, bacteria and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.
- N. "Pest" means any objectionable animal or insect including, but not limited to, birds, rodents, flies and larvae.
- O. "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling or holding of human food.
- P. "Quality Control Measure" means a planned and systematic procedure for taking actions necessary to prevent food from being adulterated.

SECTION 110.3 DEFINITIONS CONTINUED

- Q. "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- R. "Safe Moisture Level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage and distribution. The maximum safe moisture level for a food is based on its water activity (aw). Water activity will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.
- S. "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing the number of other undesirable microorganisms, but without adversely affecting the product or its safety to the consumer.
- T. "Shall" is used to state mandatory requirements.
- U. "Should" is used to state recommended or advisory procedures or to identify recommended equipment.
- V. "Water Activity" (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

SECTION 110.10 PERSONNEL.

The plant management shall take all reasonable measures and precautions to ensure the following:

- A. Disease control. Any person who, by medical examination or supervisory observations, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food packaging material becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until such condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.
- B. Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against the contamination of food. The methods for maintaining cleanliness include, but are not limited to:
1. Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
 2. Maintaining adequate personal cleanliness.

SECTION 110.10 PERSONNEL CONTINUED

3. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
 4. Removing unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of food, food-contact surfaces, or food-packaging materials.
 5. Maintaining gloves, if they are used in food handling, in an intact, clean and sanitary condition. The gloves should be made of an impermeable material.
 6. Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
 7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
 8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
 9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
- C. Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary.
- D. Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

SECTION 110.19 AGRICULTURE EXCLUSIONS

- A. The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the Federal Food Drug and Cosmetic Act, which are ordinarily cleaned prepared, treated, or otherwise processed before being marketed to the consuming public.

SECTION 110.20 PLANT AND GROUNDS

A. Grounds.

The grounds about a plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

1. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects or other pests.
2. Maintaining roads, yards, and parking lots, including dust and flying debris, so that they do not constitute a source of contamination in areas where food is exposed.
3. Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
4. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (A)(1 through 3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

B. Plant construction and design

Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

1. Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
2. Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packing materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.
3. Permit the taking of proper precautions to protect food in outdoor bulk vessels by any effective means, including:
 - i. Using protective coverings.
 - ii. Controlling areas over and around the vessels to eliminate harborages or pests.
 - iii. Checking on a regular basis for pests and pest infestation.
 - iv. Skimming the fermentation vessels, as necessary.

SECTION 110.20 PLANT AND GROUNDS CONTINUED

4. Be constructed in such a manner that the walls and ceilings may be adequately cleaned and kept clean and in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
5. Provides complete partitioning and solid self-closing doors between the food processing establishment and any directly attached room(s) used as living or sleeping quarters.
6. Provide adequate lighting in hand washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
7. Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials and food-contact surfaces.
8. Provide, where necessary, adequate screening or other protection against pests.

SECTION 110.35 SANITARY OPERATIONS

A. General maintenance

Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the Act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

B. Substances used in cleaning and sanitizing; storage of toxic materials.

- 1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
 - i. Those required to maintain clean and sanitary conditions;
 - ii. Those necessary for use in laboratory testing procedures;
 - iii. Those necessary for plant and equipment maintenance and operation; and
 - iv. Those necessary for use in the plant's operations.

SECTION 110.35 SANITARY OPERATIONS CONTINUED

- 2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, stored and used in a manner that protects against contamination of food, food contact surfaces, or food-packaging materials. All relevant regulations promulgated by Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

C. Pest control.

No pests or animals shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packing materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

D. Sanitization of food-contact surfaces

All food-contact surfaces of equipment and utensils and non-food-contact surfaces of equipment shall be cleaned and sanitized as frequently as necessary to protect against contamination of food.

- 1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
- 2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
- 3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned and sanitized as frequently as necessary to protect against contamination of food.
- 4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used and disposed of in a manner that protects against contamination of food or food-contact surfaces.
- 5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

E. Storage and handling of cleaned portable equipment and utensils.

Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

SECTION 110.37 SANITARY FACILITIES AND CONTROLS

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

A Water supply

The water supply shall be sufficient for the operations intended and shall be derived from an adequate source in compliance with applicable water supply regulations adopted by the State Board of Health. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Hot and cold running water under pressure shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

B. Plumbing

Plumbing shall be installed in accordance with the Arkansas State Plumbing Code and shall be of adequate size and design, installed and maintained to:

- 1) Carry sufficient quantities of water to required locations throughout the plant.
- 2) Properly convey sewage and liquid disposable waste from the plant.
- 3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an insanitary condition.
- 4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- 5) Provide that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry potable water for food or food manufacturing or for equipment and utensil cleaning.

C. Sewage disposal

Sewage disposal shall be made into an adequate and approved sewerage system which is in compliance with applicable wastewater disposal regulations adopted by the State Board of Health.

D. Toilet facilities

The plant shall be provided with adequate and conveniently located toilets, installed in accordance with the Arkansas State Plumbing Code. The toilet facilities shall be:

- 1) Maintained in a sanitary manner
- 2) In good repair.
- 3) Mechanically vented to the outside.
- 4) Provided with self-closing doors.

SECTION 110.37 SANITARY OPERATIONS CONTINUED

E. Hand-washing facilities

Hand-washing facilities shall be adequate and convenient and shall be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

- 1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
- 2) Effective hand-cleaning and sanitizing preparations.
- 3) Sanitary towel service or suitable drying devices.
- 4) Devices or fixtures, such as water control valves, shall be so designed and constructed as to protect against recontamination of clean, sanitized hands.
- 5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and where appropriate, sanitize their hands before they start to work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs should be posted in processing room(s) and in all other areas where employees may handle such food, materials, or surfaces
- 6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

F. Rubbish and offal disposal.

Rubbish and any offal shall be so conveyed, stored and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies and ground surfaces.

SECTION 110.40 EQUIPMENT AND UTENSILS

A. Design, fabrication, installation and maintenance

All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food contact surfaces shall be corrosion-resistant and shall be made of non-toxic materials and designed to withstand the environment of their intended use and the action of food, and if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

B. Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

C. Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

SECTION 110.40 EQUIPMENT AND UTENSILS CONTINUED

- D. Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an approved sanitary condition.
- E. Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately to within 3° F. inside the compartment, and shall be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change during manual operation.
- F. Instruments and controls used for measuring, regulating or recording temperatures, pH, acidity, water activity or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.
- G. Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

SECTION 110.80 PROCESSES AND CONTROLS

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, processing and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the Act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

A. Raw materials and other ingredients

- 1. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing or conveying shall be safe and of potable quality. Water shall not be reused for washing, rinsing or conveying if it increases the level of contamination of the food. Containers and carriers of raw materials shall be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

SECTION 110.80 PROCESSES AND CONTROLS CONTINUED

2. Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise be treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the Act. Compliance with this requirement may be verified by any approved means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
3. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with applicable Federal Food and Drug Administration regulations, guidelines, and defect action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be verified by any approved means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
4. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Federal Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any approved means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
5. Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the Act. Material scheduled for rework shall be identified as such.
6. Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the Act.
7. Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

B. Manufacturing operations

1. Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.
2. All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate and manufacturing operations such as freezing, dehydration, heat processing, acidification and refrigeration to ensure that mechanical breakdowns,

SECTION 110.80 PROCESSES AND CONTROLS CONTINUED

time delays, temperature fluctuations and other factors do not contribute to the decomposition or contamination of food.

3. Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated. Compliance with this requirement may be accomplished by any effective means, including:
 - i. Maintaining refrigerated foods at 45 degrees F. (7.2 degrees C) or below or appropriate for the particular food involved.
 - ii. Maintaining frozen foods in a frozen state.
 - iii. Maintaining hot foods at 140 degrees F. (60 degrees C) or above.
 - iv. Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.
4. Measures, such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the Act.
5. Work-in-process shall be handled in a manner that protects against contamination.
6. Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.
7. Equipment, containers and utensils used to convey, hold or store raw materials, work-in-process, rework or food shall be constructed, handled and maintained during manufacturing or storage in a manner that protects against contamination.
8. Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors or other suitable effective means.
9. Food, raw materials and other ingredients that are adulterated shall be disposed in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be re-examined and found not to be adulterated before being incorporated into other food.
10. Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food contact

SECTION 110.80 PROCESSES AND CONTROLS CONTINUED

surfaces, and by using time and temperature controls at and between each manufacturing step.

11. Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food to 45°F. or below or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water shall be safe and of adequate sanitary quality.

12. Batters, breading, sauces, gravies, dressings and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:
 - i. Using ingredients free of contamination.
 - ii. Employing adequate heat processes where applicable.
 - iii. Using adequate time and temperature controls.
 - iv. Providing adequate physical protection of components from contaminants that may drip, drain or be drawn into them.
 - v. Cooling to an adequate temperature during manufacturing.
 - vi. Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

13. Filling, assembling, packaging and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any approved means, including:
 - i. Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
 - ii. Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
 - iii. Using materials for food containers and food-packaging materials that are safe and suitable.
 - iv. Providing physical protection from contamination, particularly airborne contamination.
 - v. Using sanitary handling procedures.

14. Food such as, but not limited to, dry mixes, nuts, intermediate moisture food and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by an effective means, including employment of one or more of the following practices as appropriate:
 - i. Monitoring the aw of raw materials, food in process and finished food.
 - ii. Controlling the soluble solids-water ratio in finished food.
 - iii. Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.

15. Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored

RULES AND REGULATIONS GOOD MANUFACTURING PRACTICES

and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by an effective means, including employment of one or more of the following practices as appropriate:

1. Monitoring the pH of raw materials, food in process, and finished food.
 - n. Controlling the amount of acid or acidified food added to low-fat food.
16. When ice is used in contact with food, it shall be made from a water source in compliance with applicable water supply regulations adopted by the State Board of Health. The ice shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in these regulations. Provisions shall be made for drainage of water produced by melting ice.
17. Food-manufacturing areas and equipment used for manufacturing human food shall not be used to manufacture non-human food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.
18. Food manufacturing shall not be performed in place of human residence nor shall manufacturing areas open directly into rooms occupied as residence or sleeping quarters.
19. Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity shall be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records should be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than two years.

SECTION 110.93 WAREHOUSING AND DISTRIBUTION

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical and microbial contamination as well as against deterioration of the food and the container.

SECTION 110.110 NATURAL OR UNAVOIDABLE DEFECTS

Natural or unavoidable defects in food for human use that present no health hazard

- a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
- c) Compliance with defect action levels does not excuse violation that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturer, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, even though

SECTION 110.110 NATURAL OR UNAVOIDABLE DEFECTS

the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all time utilize quality control operation that reduces natural or unavoidable defects to the lowest level currently feasible.

- d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.
- e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that the present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition.

SECTION 111.1 PERMITS, INSPECTIONS AND PLAN REVIEW. •

A PERMITS.

1. General

No person shall operate a food processing establishment who does not have a valid food establishment permit issued to him by the Health Authority in accordance with Act 378 of 1991 (Ark. Code Ann. §§ 20-57, 201 through 20-57-205). Only a person who complies with the requirements of these Regulations shall be entitled to receive or retain a food establishment permit. Permits are not transferable. A valid permit shall be conspicuously posted in every food processing establishment.

2. Issuance of permit

Prior to the issuance of a permit the following requirements shall be met:

- a. Any person desiring to operate a food processing establishment shall make written application for a food establishment permit on forms provided by the Health Authority. Such application shall include the name and address of each applicant, the location of the proposed food processing establishment and the signature of each applicant.
- b. Prior to approval of an application for a food establishment permit, the Health Authority shall inspect the proposed food processing establishment to determine compliance with the requirements of the Regulations.
- c. The Health Authority shall issue a food establishment permit to the applicant if its inspection reveals that the proposed food processing establishment complies with the requirements of these Regulations.

3. Suspension or revocation of permit

Procedures for the suspension and/or revocation of a food establishment permit shall be in accordance with Act 434 of 1967 (Ark. Code Ann. §§ 25-15-201 through 25-15-214).

B. INSPECTIONS

Representatives of the Health authority, after proper identification, shall be permitted to enter any food manufacturing establishment or food storage warehouse at any reasonable time for the purpose of making inspections to determine compliance with these regulations.

RULES AND REGULATIONS GOOD MANUFACTURING PRACTICES

SECTION 111.1 PERMITS,INSPECTIONS AND PLANREVIEW CONTINUED

The representatives shall be permitted to examine records maintained in the establishment to obtain information pertaining to the source of food and supplies in the establishment when deemed necessary for the enforcement of these regulations.

C. PLAN REVIEW

Prior to beginning construction or extensive remodeling, plans for the proposed food processing establishment must first be submitted to the Plan Review Section of the Health Authority for review and approval. A pre-opening inspection must be conducted by the Health Authority to assure that construction has been accomplished in accordance with the approved plans.

SECTION 111.2 SPECIAL RISK SITUATIONS

A EMERGENCY OCCURANCES

The person in charge of a food establishment that is affected by a fire, flood, extended power outage or a similar significant occurrence that creates a reasonable probability that food in the food establishment may have been contaminated or that the temperature level of the food which is in a potentially hazardous form may have caused that food to have become hazardous to health, shall take such action as is necessary to protect the public health and shall promptly notify the Arkansas Department of Health of the emergency. Upon receiving such notice of this occurrence, the Health Authority shall take action deemed necessary to protect the public health.

B. INFECTION

When the Arkansas Department of Health has reasonable cause to suspect possible disease transmission by an employee of a food processing establishment, the Department may secure a morbidity history of the employee or make any other investigation as indicated and shall take appropriate action. The Arkansas Department of Health may require at a minimum any or all of the following measures:

1. The immediate exclusion of the employee from employment in food establishments;
2. The immediate closing of the food establishment concerned until no further danger of disease outbreak exists;
3. Restriction of the employee's services to some area ofthe establishment where there would be no danger oftransmitting disease;
4. Adequate medical laboratory examination ofthe employee and other employees and ofhis and their body discharges.

SECTION 111.3 PENALTIES AND INJUNCTIONS

A. PENALTIES

Penalties for violations of these Rules and Regulations may be imposed as provided in (Ark. Code Ann. § 20-7-101).

B. INJUNCTIONS

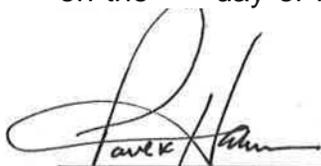
The Health Authority may seek to enjoin violations of the Regulations.

SECTION 111.4 REPEAL

All Regulations and parts of Regulations in conflict herewith are hereby repealed.

CERTIFICATION

This will certify that the foregoing Rules and Regulations Pertaining to Retail Food Establishments were adopted by the Arkansas Department of Health at the regular session of the Board of Health held at Winthrop Rockefeller Institute, Petit Jean Mountain, Arkansas on the day of November, 2012.



Paul K. Halverson, DrPH, FACHE
Secretary, State Board of Health